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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,066

01/27/2006

Paul D. Wightman

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EXAMINER

WARD, PAUL V

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

01/26/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

Office Action Summary	Application No. 10/595,066	Applicant(s) WIGHTMAN, PAUL D.	
	Examiner PAUL V. WARD	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,11,13,14,17,18,20,21,24,25,28,29 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 25,28,29,34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,11,13,14,17,18,20,21,24 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, in the reply filed on September 25, 2008 is acknowledged. The traversal is on the ground that groups I-VI are inter-related (i.e., part of one and the same invention), and thus, would not be unduly burdensome. This is not found persuasive because Groups I-VI are separate and patentably distinct because there is no patentable co-action among them. For example when R_A and R_B form a fused aryl ring or when R_A and R_B form a fused six-membered heterocyclic ring with one nitrogen, a reference anticipating one will not render the other obvious. Hence, Applicant's inventions are distinct and have acquired a separate status in the art due to their recognized divergent subject matter and different classification. Additionally, because each group has different subclasses, it would constitute a burden on the Examiner to search all subclasses. Further, different fields of search would be required in the non-patent literature. Thus, a search of the twelve groups would impose an undue burden upon the Examiner. Therefore, the restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

Groups I and III-XII is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant reserved the right to file a divisional application to the non-elected subject matter.

Applicant is entitled to have the method claims rejoined under M.P.E.P. § 821.04, if the compounds and pharmaceutical composition claims of Group II are allowable.

An action on the merits on claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 is contained herein.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 1 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 20 define variables (where applicable) as aryl, heteroaryl, and heterocyclyl. The terms are indefinite since the specification does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the atom(s) for the substituents. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

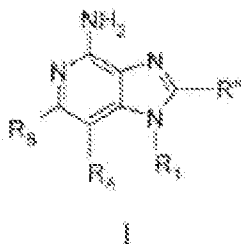
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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Kedl et al. (U.S. Patent 7,427,629).

Applicant teaches imidazo-quinolinyl compounds as immune response modifiers for treating various diseases. Applicant claims a compound with a general formula I:



wherein all the variables are as defined in the claim. Additionally, Applicant claims pharmaceutical compositions comprising the compound of formula I.

Kedl discloses imidazo-quinolinyl compounds, which share the same formulaic compounds. (See formula 1, col. 8). The compounds in the said patent has the same structure, which includes R_A and R_B as a fused aryl ring, R^1 as an alkenylene or alkylene, and as H, alkyl alkenyl, alkylene-Y-alkyl, and falls within the range of Applicant's compounds. (See columns 8-10 and 17). Additionally, in col. 6, lines 40-49, Kedl teaches the pharmaceutical composition comprising the compound of formula I. Since Kedl teaches the exact compounds and compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(e).

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3. Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hays et al. (U.S. Patent 7,091,214).

Hays discloses imidazo-quinolinyll compounds, which share the same formulaic compounds. (See formula 1, col. 1). The compounds in the said patent has the same structure, which includes R_A and R_B as a fused aryl ring, R¹ as an alkenylene or alkylene, and as H, alkyl alkenyl, alkylene-Y-alkyl, and falls within the range of Applicant's compounds. (See columns 3-20 and Examples 1-14). Additionally, in col. 48, lines 45-67, Hayes teaches the pharmaceutical composition comprising the compound of formula I. Since Hayes teaches the exact compounds and compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kedl et al. (U.S. Patent 7,427,629).

Claim 1 is drawn to imidazo-quinolinyl compounds in which the moieties on the imidazo-quinolinyl compounds core contain at least one H, alkylene, alkenylene, alkyl and N moieties and a 5 to 7 fused aryl ring moiety. The 5 to 7-membered fused aryl ring moieties are substituted by variables represented by R groups, which are represented by H, halogen, hydroxyl, alkyl, alkenyl, haloalkyl, alkoxy alkylthio substituents of various carbon lengths which may be further substituted.

DETERMINING THE SCOPE AND CONTENT OF THE PRIOR ART

Kedl teaches a compound with imidazo-quinolinyl core which corresponds in structure with the instantly claimed compound of formula I. The one H, alkylene, alkenylene, alkyl and N moieties and a 5 to 7 fused aryl ring moiety of said prior art core are substituted by variables represented by R groups, which are independently represented by R₁-R₅, which are represented by H, alkylene, alkenylene, alkyl and N.

ASCERTAINING THE DIFFERENCES BETWEEN THE PRIOR ART AND THE CLAIMS AT ISSUE

The instant claims differ from the reference by reciting different carbon ranges and substituents for the overlapping moieties attached to the core of the compound through the imidazo-quinolinyl core and the prior art compound does not require other moieties to be attached to the core but provides sufficient support for such a substitution on the core.

CONSIDERING OBJECTIVE EVIDENCE PRESENT REGARDING OBVIOUSNESS

The prior art reference clearly discloses the class of compounds instantly claimed, which are imidazo-quinolinyl compounds, are recognized in the art by their correlative core and recognized suitability for use in immune response pathways containing said imidazo-quinolinyl compounds. These compounds are known to be included in immune response functions, such as modifiers. The variable substitution to the core of the prior art's compound and the compound instantly claimed overlap so substantially that it would require little more than routine skill in the art to select moieties which would allow the skilled artisan to arrive at applicant's instantly claimed species.

RESOLVING THE LEVEL OF SKILL IN THE ART

It would have been obvious to one having ordinary skill in this art at the time the invention was made to substitute a imidazo-quinolinyl core containing group and with the groups set forth in the prior art as applicant has done with the above cited reference before them. The prior art patent provides sufficient motivation to include the compounds of the prior art and those rendered obvious in the instant application in a compound used in immune response functions.

Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

5. Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hays et al. (U.S. Patent 7,091,214).

Claim 1 is drawn to imidazo-quinolinyl compounds in which the moieties on the imidazo-quinolinyl compounds core contain at least one H, alkylene, alkenylene, alkyl

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and N moieties and a 5 to 7 fused aryl ring moiety. The 5 to 7-membered fused aryl ring moieties are substituted by variables represented by R groups, which are represented by H, halogen, hydroxyl, alkyl, alkenyl, haloalkyl, alkoxy alkylthio substituents of various carbon lengths which may be further substituted.

DETERMINING THE SCOPE AND CONTENT OF THE PRIOR ART

Hayes teaches a compound with imidazo-quinoliny core which corresponds in structure with the instantly claimed compound of formula I. The one H, alkylene, alkenylene, alkyl and N moieties and a 5 to 7 fused aryl ring moiety of said prior art core are substituted by variables represented by R groups, which are independently represented by R₁-R₅, which are represented by H, alkylene, alkenylene, alkyl and N.

ASCERTAINING THE DIFFERENCES BETWEEN THE PRIOR ART AND THE CLAIMS AT ISSUE

The instant claims differ from the reference by reciting different carbon ranges and substituents for the overlapping moieties attached to the core of the compound through the imidazo-quinoliny core and the prior art compound does not require other moieties to be attached to the core but provides sufficient support for such a substitution on the core.

CONSIDERING OBJECTIVE EVIDENCE PRESENT REGARDING OBVIOUSNESS

The prior art reference clearly discloses the class of compounds instantly claimed, which are imidazo-quinoliny compounds, are recognized in the art by their correlative core and recognized suitability for use in immune response pathways containing said imidazo-quinoliny compounds. These compounds are known to be included in immune response functions, such as modifiers. The variable substitution to

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the core of the prior art's compound and the compound instantly claimed overlap so substantially that it would require little more than routine skill in the art to select moieties which would allow the skilled artisan to arrive at applicant's instantly claimed species.

RESOLVING THE LEVEL OF SKILL IN THE ART

It would have been obvious to one having ordinary skill in this art at the time the invention was made to substitute a imidazo-quinoliny core containing group and with the groups set forth in the prior art as applicant has done with the above cited reference before them. The prior art patent provides sufficient motivation to include the compounds of the prior art and those rendered obvious in the instant application in a compound used in immune response functions.

Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Conclusion

Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 are pending. Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24 and 33 are rejected. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/PAUL V WARD/

Examiner, Art Unit 1624

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624